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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,352	08/19/2005	Jan Matthias Braun	5008.01US01	3048

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,352	BRAUN ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner would like to note that upon further review the following Restriction Requirement is being set forth.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 (in part), 2, 4, 6, 7, 10, 11, and 12, drawn to a medicament comprising glycoconjugates or lipoligosaccharides (LOS) purified or included in outer membrane vesicles, blebs, lipid layers, lipoosomes and/or killed bacterial from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup A, B, C, H, I, K, L, X, Y, Z, 29E or W135, or non-capsulated meningococcal strains.

Group II, claim(s) 1(in part), 5-10 and 22, drawn to a medicament comprising antibodies against glycoconjugates or lipooligosaccharides.

Group III, claim(s) 3 and 12-18, drawn to a medicament comprising glycoconjugates or lipoligosaccharides (LOS) purified or included in outer membrane vesicles, blebs, lipid layers, lipoosomes and/or killed bacterial from commensal *Neisseria lactamica* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B, C, H, I, K, L, X, Y, Z, 29E or W135, or non-capsulated meningococcal strains, wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive to human blood group antigens or antibodies against such oligosaccharides of LOS.

Group IV, claim(s) 19, drawn to a method of treating a patient comprising providing a patient with the medicament comprising glycoconjugates or lipoligosaccharides (LOS) purified or included in outer membrane vesicles, blebs, lipid layers, lipoosomes and/or killed bacterial from commensal *Neisseria lactamica* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B, C, H, I, K, L, X, Y, Z, 29E or W135, or non-capsulated meningococcal strains, wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive to human blood

group antigens or antibodies against such oligosaccharides of LOS for passive immunization, in combination with sodium selenite or with an adjuvant.

Group V, claim(s) 20, drawn to a method of treating a patient comprising providing a medicament comprising glycoconjugates or lipoligosaccharides (LOS) purified or included in outer membrane vesicles, blebs, lipid layers, lipoosomes and/or killed bacterial from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup A, B, C, H, I, K, L, X, Y, Z, 29E or W135, or non-capsulated meningococcal strains to a patient diagnosed with acute meningitis.

Group VI, claim(s) 20, drawn to a drawn to a method of treating a patient comprising providing a medicament comprising antibodies against glycoconjugates or lipooligosaccharides to a patient diagnosed with acute meningitis.

Group VII, claim(s) 21, drawn to a method of treating a patient comprising providing a medicament comprising glycoconjugates or lipoligosaccharides (LOS) purified or included in outer membrane vesicles, blebs, lipid layers, lipoosomes and/or killed bacterial from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup A, B, C, H, I, K, L, X, Y, Z, 29E or W135, or non-capsulated meningococcal strains to a patient diagnosed with septicemia.

Group VIII, claim(s) 21, drawn to a method of treating a patient comprising providing a medicament comprising antibodies against glycoconjugates or lipooligosaccharides to a patient diagnosed with septicemia.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason: The products of Groups I-III are not made by the methods of Groups IV-VIII as claimed.

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited **product**. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the

meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature lacks novelty under PCT Article 33(2), for example, over Gu et al. (U.S. Patent 6,685,949 B1). Gu et al. disclose a medicament that includes lipooligosaccharides (LOS) derived from *Moraxella catarrhalis* (see column 4, lines 22-27).

Additional Election Requirement

Each Group detailed above reads on patentably distinct compositions. Each composition is patentably distinct because they comprise genes with differing genus, species, antibodies, and source of antibodies and a further restriction is applied to each Group. (See MPEP 803.04).

Should Applicant elect Groups I, III, IV, VI or VII Applicant must elect a combination of glycoconjugates, lipooligosaccharides, specific bacterium, and the specific antigen it cross-reacts.

Should Applicant elect Group II, VI, or VIII Applicant must further elect a specific antibody, a specific antigen to which antibody was raised or the source of the antibody.

Applicant is advised that examination will be restricted to only the elected sequence and/or disease and should not be construed as a species election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
8/2/07

ROBERT A. ZEMAN
PRIMARY EXAMINER